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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,009	08/06/2002	Carolyn K. Goldman	NIH-05111	5287

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,009	GOLDMAN ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,9-15,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-5, 9-15, 22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's amendment filed on 22 November 2004 is acknowledged and entered. Following the amendment, claims 2, 6-8 and 16-21 are canceled, and claims 1, 3, 9, 12 and 13 are amended, and the new claims 22 and 23 are added.

Currently, claims 1, 3-5, 9-15, 22 and 23 are pending and under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claim 2 are moot as the applicant has canceled the claim.

The prior art rejection of claims 1-4 and 9-15 under 35 U.S.C. 102(b) as being anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cerretti et al., EP 0 162 699, and as evidenced by Colamonici et al. (J. Immunol., 1990, 145:155-160) is withdrawn in view of applicant's amendment.

Formal Matters:

Claims

Claims 13 is objected to for the following informalities, appropriate correction is required for each item:

In line 3 of the claim, the term "cells lines" should be "cell lines".

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-5 and 9-15 remain rejected, and the new claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth in the last Office Action mailed on 03 June 2004, at page 3.

Applicants argument filed on 22 November 2004 has been fully considered, but is not deemed persuasive for reasons below.

At page 5 of the response, the applicant argues that claim 1 has been amended to recite molecular weight of the polypeptide and how it is determined. However, such addition is still not adequate for pointing out that which applicants see as their invention because polypeptides with distinct structures may have the same MW and share same epitopes. The metes and bounds of the claim, therefore, still cannot be determined.

At page 6 of the response, the applicant argues that the term "reactive" is understood by those having ordinary skill in the art to mean, in the context of the instant application, the ability of an antibody to recognize and/or interact with the subject polypeptides. This argument is not persuasive because although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, the specification does not even define "reactive", thus, there is nothing to "read into" the claims. Furthermore, it is well established in the art that non-specific binding happens for antibodies, which would be a type of "reactive" or "interact". Applicants further argue, with respect to missing the method steps in claims 9-11, that the language in MPEP 2172.02, which the Office relies, is directed to the enablement requirement rather than the indefiniteness requirement as set forth by the Office, and thus, an indefiniteness rejection is not proper. This argument is not persuasive because MPEP 2172.01 (not 2172.02) further indicate that "[I]n addition, a claim which fails to interrelate essential elements of the invention as defined by applicant(s) in the specification may be rejected under 35 U.S.C. 112, second.

At pages 7 of the response, the applicant argues, with respect to "said cells ... are solubilized prior to said contacting of said cells with said antibody " in claim 10, that the Office states that "it is impossible to contact said *cells* after solubilization, as said "cells" would not exist anymore", and then go on to directly contradict its position in the prior art rejection by stating that Cerretti discloses "a method for purifying the polypeptide by using an antibody ..., wherein the method involves solubilization of the cells, contacting with said antibody ... and eluting", and that accordingly, the language of claim 10, in light of the prior art, particularly points out and distinctly claims the inventive method, although the office alleges it is impossible. This argument is not persuasive for the following reasons. First, the prior art never teaches to contact *cells* with the antibody after solubilization, it was cell *extract* used for the experiment. Further,

even if the prior had said so, a false statement against the fact would not have made the instant claim language correct or proper, especially within the meaning of patentability because the fact is that after solubilization, the structure of cells would be destroyed, thus there is no *cells* to contact. Also, art is applied to the broadest reasonable interpretation of the claims despite the indefiniteness of the claim language.

The remaining claims remain rejected for depending from an indefinite claim.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5, 9, 10, 13-15 remain rejected, and the new claims 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Colamonici et al. (J. Immunol., 1990, 145:155-160), for the reasons of record set forth in the last Office Action mailed on 03 June 2004, at page 6.

Applicants argument filed on 22 November 2004 has been fully considered, but is not deemed persuasive for reasons below.

At pages 8-9 of the response, the applicant argues that the prior art products do not necessarily possess the characteristics of the claimed product because, first, the molecular mass of any polypeptide identified by Colamonici does not fall with in the range of that recited for either of the subject polypeptides, 32-34 and 26-28 kDa even though the same technique was used to determine molecular mass, and second, Colamonici states that "these bands might correspond to 2, or even 3 novel proteins," and that it is possible that these bands correspond to degradation products of the 55 kDa protein. This argument is not persuasive for the following reasons. With respect to the first point, the present claims 1 and 3 recite "a molecular weight of *about* " 32 to 34 kDa, and 26 to 28 kDa, respectively, and thus, a molecular weight of 37 kDa (the prior art) is clearly "about" 34 kDa, and a molecular weight of 20 kDa is clearly "about" 26 kDa (or vice versa). Further, the slight difference in molecular weight determined by SDS-PAGE between Colamonici's proteins and applicants is merely a few kDa (37 vs. 34 kDa, and 20 vs. 26 kDa), which can be easily explained by experimental variations in the absence of evidence to the contrary. For example, different gel concentrations and running time may cause the same molecule to migrate differently with respect to the determination of its molecular weight. Therefore, the difference in molecular weight in the instant situation is not sufficient to support that they are different molecules in the absence of other evidence such as sequence structure and/or different sources of isolation. With respect to applicants second point, contrary to applicants own interpretation that that it is possible that these bands correspond to degradation products of the 55 kDa protein, Colamonici teaches that "we consider *it unlikely* that these bands correspond to degradation products of p55, since they were present even when a cocktail of protease inhibitors was used", and that these bands might correspond to 2 or even 3 novel proteins very closely associated with p55 (page 159, the last paragraph). Therefore, not only Colamonici confirms that those bands are not degradation products of the 55 kDa protein, but also indicates the association of the lower molecular weight proteins with the 55 kDa protein (α subunit of IL-2R). Thus, Colamonici's lower molecular weight proteins indeed possess the characteristics of the presently claimed product. Once again, for the reasons addressed in the last Office Action and above, the burden shifts to the applicant to provide *evidence* that the prior art

would neither anticipate nor render obvious the claimed invention. Note the case law of *In re Best* 195 USPQ 430, 433 (CCPA 1977).

At pages 9-10 of the response, the applicant argues that the burden on the examiner to provide rationale or evidence making clear that the missing limitation is necessarily present in the reference, that the Examiner has not mentioned the concept of inherency, and has not met the burden for rejecting the instant claims under 35 U.S.C. 102/103. This argument is not persuasive for reasons above.

Conclusion:

No claim is allowed.

Advisory Information:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
4/8/05